EXHIBIT A

Case 5:21-cv-03177-JMG Document 1-1 Filed 07/16/21 Page 2 of 29

Trial Division		For Protho	For Prothonotary Use Only (Docket Number)		
		JULY 2021	JULY 2021 004 200		
Civil Cover Sheet		E-Filing Number: 21070287		001200	
PLAINTIFF'S NAME KEVIN HAMBLIN		DEFENDANT'S NAME B. BRAUN MEDICAL,			
PLAINTIFF'S ADDRESS 1936 S. OCEAN DRIVE, APT. A5 HALLANDALE BEACH FL 33009-2005		DEFENDANT'S ADDRESS 824 12TH AVENUE BETHLEHEM PA 1801	DEFENDANT'S ADDRESS 824 12TH AVENUE BETHLEHEM PA 18018		
PLAINTIFF'S NAME		DEFENDANT'S NAME B. BRAUN INTERVEN	DEFENDANT'S NAME B. BRAUN INTERVENTIONAL SYSTEMS, INC.		
PLAINTIFF'S ADDRESS		DEFENDANT'S ADDRESS 824 12TH AVENUE BETHLEHEM PA 1801	DEFENDANT'S ADDRESS 824 12TH AVENUE BETHLEHEM PA 18018		
PLAINTIFF'S NAME		DEFENDANT'S NAME B. BRAUN MEDICAL	DEFENDANT'S NAME B. BRAUN MEDICAL S.A.S.		
PLAINTIFF'S ADDRESS		I	DEFENDANT'S ADDRESS 204 AVENUE DU MARECHAL JUIN BOULOGNE-BILLANCOURT		
TOTAL NUMBER OF PLAINTIFFS TOTAL	TAL NUMBER OF DEFENDANTS 3	COMMENCEMENT OF ACTION IZ Complaint Petition Writ of Summons Transf	on Action [☐ Notice of Appeal	
□ \$50,000.00 or less □ Arl □ Jur ■ More than \$50,000.00 □ No	y 🔲 Savir	X Mass Tort ☐ Commerce ☐ Settlement ☐ Savings Action ☐ Minor Court Appeal ☐ Minors ☐ Petition ☐ Statutory Appeals ☐ W/D/Survival			
CASE TYPE AND CODE XV - MT - VENA CAVA FILTER					
STATUTORY BASIS FOR CAUSE OF ACTION					
RELATED PENDING CASES (LIST BY CASE CAPTION AND DOCKET NUMBER)		PRO PROTHY	IS CASE SUBJECT COORDINATION C YES	ORDER?	
	JUL 15 2021				
		S. RICE			
TO THE PROTHONOTARY:					
Kindly enter my appearance on behalf of Plaintiff/Petitioner/Appellant: KEVIN HAMBLIN					
Papers may be served at the addr	ess set forth below.				
NAME OF PLAINTIFF'S/PETITIONER'S/APPELLANT'S ATTORNEY		ADDRESS			
BEN C. MARTIN			3141 HOOD STREET SUITE 600		
PHONE NUMBER (214) 761-6614	FAX NUMBER (214) 744-7590	DALLAS TX 75219			
SUPREME COURT IDENTIFICATION NO. 320123		E-MAIL ADDRESS bmartin@martinba	E-MAIL ADDRESS bmartin@martinbaughman.com		
SIGNATURE OF FILING ATTORNEY OR PARTY BEN MARTIN		DATE SUBMITTED Thursday, July	Thursday, July 15, 2021, 07:31 pm		



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Attorneys for Plaintiff

KEVIN HAMBLIN, an individual, : **COURT OF COMMON PLEAS**

: PHILADELPHIA COUNTY

Plaintiff, :

•

v. : JULY TERM, 2021

: DOCKET NO.____

B. BRAUN MEDICAL, INC., a

Pennsylvania corporation; B. BRAUN

INTERVENTIONAL SYSTEMS, INC., a Delaware corporation; and B. BRAUN

MEDICAL S.A.S., a French corporation,

Defendants.

JURY TRIAL DEMANDED

FIRST JUDICIAL DISTRICT OF PENNSYLVANIA

COURT OF COMMON PLEAS OF PHILADELPHIA

NOTICE TO DEFEND

NOTICE

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint of for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

You should take this paper to your lawyer at once. If you do not have a lawyer or cannot afford one, go to or telephone the office set forth below to find out where you can get legal help.

Philadelphia Bar Association Lawyer Referral and Information Service One Reading Center Philadelphia, Pennsylvania 19107 (215) 238-6333 TTY (215) 451-6197

AVISO

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usted tiene veinte (20) dias de plazo al partir de la fecha de la demanda y la notificacion. Hace falta ascentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificacion. Ademas, la corte puede decider a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted.

Lleve esta demanda a un abogado immediatamente. Si no tiene abogado o si no tiene el dinero suficiente de pagar tal servicio. Vaya en persona o llame por telefono a la oficina cuya direccion se encuentra escrita abajo para averiguar donde se puede conseguir asistencia legal.

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KEVIN HAMBLIN, an individual, : **COURT OF COMMON PLEAS**

: PHILADELPHIA COUNTY

Plaintiff, :

v. : JULY TERM, 2021

: **DOCKET NO.**_____

: JURY TRIAL DEMANDED

B. BRAUN MEDICAL, INC., a

Pennsylvania corporation; B. BRAUN

INTERVENTIONAL SYSTEMS, INC., a Delaware corporation; and B. BRAUN

MEDICAL S.A.S., a French corporation,

:

Defendants.

COMPLAINT

Plaintiff Kevin Hamblin, by and through his undersigned attorney, hereby sues defendants B. Braun Medical, Inc., B. Braun Interventional Systems, Inc., and B. Braun Medical S.A.S., and alleges as follows:

PARTIES

- 1. Plaintiff Kevin Hamblin (hereinafter "Plaintiff") is and was, at all times relevant to this action, a resident and citizen of the State of Florida, residing at 1936 S. Ocean Drive, Apt A5, Hallandale Beach, Florida, 33009-2005
- 2. Defendant B. Braun Medical, Inc. is a Pennsylvania corporation. At all times relevant to this action, B. Braun Medical, Inc. designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and/or sold the inferior vena cava filter known as the VenaTech[©] Filter System to be implanted into patients throughout the United States, including Florida. At all times relevant hereto, Defendant B. Braun Medical, Inc. was a citizen of the State of Pennsylvania, was engaged in business in Pennsylvania and conducted substantial business activity in Pennsylvania. Defendant has also carried on solicitations or service activities in Pennsylvania.
- 3. Defendant B. Braun Interventional Systems, Inc., a subsidiary, division, affiliate, or sister corporation of B. Braun Medical, Inc., is a Delaware corporation with a principal place of business located in Pennsylvania. At all times relevant to this action, B. Braun Interventional Systems, Inc. designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and/or sold the inferior vena cava filter known as the VenaTech[©] Filter System to be implanted into patients throughout the United States, including Florida. At all times relevant hereto, Defendant B. Braun Interventional Systems, Inc. was a citizen of the State of Pennsylvania, was engaged in business in Pennsylvania and conducted substantial business activity in Pennsylvania.
- 4. Defendant B. Braun Medical S.A.S., a subsidiary, division, affiliate, or sister corporation of B. Braun Medical, Inc. and B. Braun Interventional Systems, Inc., is a French

corporation. At all times relevant to this action, B. Braun Medical S.A.S. designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and/or sold the inferior vena cava filter known as the VenaTech[©] Filter System to be implanted into patients throughout the United States, including Florida. At all times relevant hereto, Defendant B. Braun Medical S.A.S. was engaged in business in Pennsylvania and conducted substantial business activity in Pennsylvania.

- 5. At all times alleged herein, B. Braun Medical, Inc., B. Braun Interventional Systems, Inc., and B. Braun Medical S.A.S. (hereinafter "Braun Defendants") include and included any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.
- 6. At all times herein mentioned, each of the Braun Defendants was the agent, servant, partner, predecessors in interest, and joint venturer of each other and were at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, joint enterprise and/or joint venture.

JURISDICTION AND VENUE

7. Personal jurisdiction is proper pursuant to 42 Pa.C.S. §§ 931 and 5301. B. Braun Medical, Inc. is incorporated in Pennsylvania. The Braun Defendants have conducted and continue to conduct substantial and systematic business activities related to their inferior vena cava filters (hereinafter "IVC filter"), including the VenaTech® Filter System (hereinafter "VenaTech filter") at issue in this case, in this jurisdiction. Such activities include, but are not limited to: (a) sales of IVC filters, including the VenaTech filter at issue in this case, in this jurisdiction; (b)

hiring, training and deploying employees, including managers and sales representatives in this jurisdiction; (c) advertising and marketing of their IVC filters, including the VenaTech filter at issue in this case, in this jurisdiction; (d) maintenance of company files and equipment relating to the VenaTech filter in this case, in this jurisdiction; (e) payment of employee salaries in this jurisdiction; and, (f) maintenance of a website directed to all states, including Florida.

- 8. Venue is properly laid in Philadelphia County pursuant to Pa.R.C.P. 1006 and 2179(a)(2), as the Braun Defendants' regularly conduct business in the county.
- 9. Plaintiff's claims in this action are brought solely under state law. Plaintiff does not herein bring, assert, or allege, either expressly or impliedly, any causes of action arising under any federal law, statute, regulation, or provision. Thus, there is no federal jurisdiction in this action on the basis of a federal question under 28 U.S.C. § 1331.
- 10. Furthermore, the Braun Defendants are citizens of Pennsylvania therefore the cause of action may not be removed. *See* 28 U.S.C. § 1441(b)(2).

ALTERNATIVE ALLEGATIONS

11. To the extent any allegation herein is inconsistent with any other allegation, such inconsistent allegations are pleaded in the alternative pursuant to Pa.R.C.P. 1020(c). *See also Baron v. Bernstein*, 106 A.2d 668, 669 (Pa. Super. 1954) (permitting inconsistent or conflicting causes of action.).

GENERAL FACTUAL ALLEGATIONS

12. Plaintiff brings this case for serious, life-threatening injuries he suffered as a result of the Braun Defendants' surgically implanted medical device, the VenaTech filter, that was implanted into Plaintiff on or about April 18, 2011. The purpose of implanting the filter was to

prevent Plaintiff from thromboembolic events. The VenaTech filter was implanted in Rochester, Minnesota, at the Mayo Clinic, 200 1st Street, SW, Rochester, Minnesota 55905.

- 13. Braun Defendants design, research, develop, manufacture, test, market, advertise, promote, distribute, and sell products such as IVC filters that are sold to and marketed as permanent devices to prevent, among other things, recurrent pulmonary embolism via placement in the vena cava. One such product is the VenaTech filter.
- 14. Braun Defendants sought U.S. Food and Drug Administration ("FDA") clearance to market the VenaTech filter device and/or its components under Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended by the Medical Devices Amendments of 1976.
- 15. On or about May 18, 2001, Defendants obtained FDA clearance to market the VenaTech filter under Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended by the Medical Devices Amendments of 1976.
- 16. Section 510(k) allows marketing of medical devices if the manufacturer claims the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of said device. The device is then cleared by the FDA under Section 510(k).
- 17. An IVC filter like the VenaTech filter is a device ostensibly designed to filter blood clots (called "thrombi") that would otherwise travel from the lower portions of the body to the heart and lungs. VenaTech IVC filters are marketed as being safely implanted permanently within the vena cava.
- 18. The inferior vena cava is a vein that returns blood to the heart from the lower portion of the body. In certain people, and for various reasons, thrombi travel from vessels in the legs and pelvis, through the vena cava into the lungs. These thrombi can develop in the deep leg veins. The

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thrombi are called "deep vein thrombosis" or DVT. If the thrombi reach the lungs, they are considered "pulmonary emboli" or PE.

- 19. An IVC filter, like the VenaTech filter, is ostensibly designed to prevent thromboembolic events by filtering or preventing blood clots/thrombi from traveling to the heart and/or lungs.
 - 20. The VenaTech filter is marketed and sold as a permanent filter.
- 21. The VenaTech filter is conical in shape, is made of PhynoxTM (a.k.a. Elgloy[©]) wires, a cobalt-chromium-nickel alloy, and can be placed through a sheath. It also has side hooks that enable the filter to fix into place.
- 22. On or about April 18, 2011, Plaintiff was implanted with a Braun VenaTech filter.

 The VenaTech filter placed into Plaintiff was represented to be safe for permanent placement.
- 23. On July 28, 2017, Plaintiff underwent a computerized tomography scan ("CT scan") of his abdomen and pelvis.
- 24. On January 8, 2019, a review of the July 28, 2017, CT scan was preformed, revealing the filter was in fact tilted, with multiply struts perforating the IVC.
- 25. Plaintiff's injury was inherently undiscoverable or objectively verifiable such that, despite Plaintiff's reasonable diligence, he was unable to discover his injury until on or after January 8, 2019, when the review of the July 28, 2017, CT scan was performed.
- 26. Plaintiff is at risk for future pulmonary embolisms, migrations, and perforations from the retained VenaTech filter, and faces numerous health risks, including the risk of death. Plaintiff will require ongoing medical care and monitoring for the rest of his life.

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- 27. At all times relevant hereto, the VenaTech filter was widely advertised and promoted by Braun Defendants as a safe and effective treatment for prevention of recurrent pulmonary embolism via placement in the vena cava.
- 28. At all times relevant hereto, Braun Defendants knew its permanent IVC filters were defective and knew that the defect was attributable to the design's failure to withstand the normal anatomical and physiological loading cycles exerted in vivo.
- 29. The Braun Defendants failed to disclose to physicians, patients, or Plaintiff that its permanent IVC filters, including the VenaTech filter, were subject to breakage, collapse, causing thrombus, and/or the appropriate degree of risk of damage to the vena cava wall.
- 30. At all times relevant hereto, Braun Defendants continued to promote their permanent IVC filters, including the VenaTech filter, as safe and effective, even though the clinical trials that had been performed were not adequate to support long or short-term efficacy.
- 31. Braun Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the permanent IVC filters, including the VenaTech filter, as aforesaid.
- 32. Braun Defendants specifically advertise the construction of the filter as "effective [for] clot trapping and preservation of caval patency."
- 33. The failure of the VenaTech filter is attributable in part to the fact that the Braun permanent IVC filters, including the VenaTech filter, suffer from a design defect causing the filters to be unable to withstand the normal anatomical and physiological loading cycles exerted in vivo.
- 34. At all times relevant hereto, Braun Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the VenaTech filter, including, but not limited to, the

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design's failure to withstand the normal anatomical and physiological loading cycles exerted in vivo.

- 35. The VenaTech filter was designed, manufactured, distributed, sold, and/or supplied by Braun Defendants, and was marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of Braun Defendants' knowledge of the product's failure and serious adverse events.
- 36. At all times relevant hereto, the officers and/or directors of Braun Defendants named herein participated in, authorized, and/or directed the production and promotion of the aforementioned products when they knew or should have known of the hazardous and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by Plaintiff.

DEFENDANTS' VENATECH FILTER IS A 510(k) CLEARED MEDICAL DEVICE

- 37. Defendants submitted premarket notification and obtained marketing clearance for its VenaTech filter from the FDA under § 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDCA"). *See* 21 U.S.C. § 360 et seq.
- 38. Pursuant to § 510(k)'s approval process, the FDA determined that Defendants' VenaTech filter was "substantially equivalent" to devices that have been reclassified in accordance with the provisions of the FDCA and did not require FDA approval of a Premarket Approval application (PMA).

DISCOVERY RULE AND FRAUDULENT CONCEALMENT

39. Plaintiff incorporates by reference the factual portion of his complaint as if fully set forth herein and additionally, or in the alternative, if same be necessary, alleges as follows.

- 40. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiff had been injured, the cause of the injury, and the tortuous nature of the wrongdoing that caused the injury.
- 41. Despite diligent investigation by Plaintiff into the cause of his injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages and their relationship to the VenaTech filter and Defendants' wrongful conduct was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.
- 42. Any applicable statutes of limitation have been tolled by the knowing and active concealment and denial of material facts known by the Braun Defendants when they had a duty to disclose those facts. The Braun Defendants' purposeful and fraudulent acts of concealment have kept Plaintiff ignorant of vital information essential to the pursuit of his claims, without any fault or lack of diligence on Plaintiff's part, for the purpose of obtaining delay on Plaintiff's part in filing on his causes of action. The Braun Defendants' fraudulent concealment did result in such delay.
- 43. The Braun Defendants are estopped from relying on the statute of limitations defense because Defendants failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of the VenaTech filter.
- 44. The Braun Defendants were, and remain, under a continuing duty to disclose the true character, quality and nature of the device that was implanted in Plaintiff, but instead they

concealed these facts. The Braun Defendants' conduct, as described in the complaint constitutes purposely committed conduct, which they must have realized was dangerous, heedless, and reckless, without regard to the consequences or the rights and safety of Plaintiff.

CORPORATE/VICARIOUS LIABILITY

- 45. At all times herein mentioned, the Braun Defendants were agents, servants, partners, aiders and abettors, co-conspirators and/or joint venturers, and were at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy, and/or joint venture and rendered substantial assistance and encouragement to each other, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.
- 46. There currently exists, and at all times herein mentioned there existed, a unity of interest in ownership between the Braun Defendants such that any individuality and separateness between them has ceased and these Defendants are alter egos. Adherence to the fiction of the separate existence of these Defendants as entities distinct from each other will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.
- 47. At all times herein mentioned, the Braun Defendants collectively, and each of them individually, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by the Plaintiff. As such, each Defendant is individually, as well as jointly and severally, liable to the Plaintiff for Plaintiff's damages.
- 48. At all times herein mentioned, the officers and/or directors of the Braun Defendants named herein participated in, authorized and/or directed the production and promotion of the

aforementioned products when they knew, or with the exercise of reasonable care and diligence, should have known of the hazards and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiff.

COUNT I <u>NEGLIGENCE</u>

- 49. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.
- 50. At all times relevant to their cause of action, Defendants were in the business of designing, developing, setting specifications, manufacturing, marketing, selling, and distributing the VenaTech filter.
- 51. Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the VenaTech filter that was implanted in Plaintiff.
- 52. Defendants had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the VenaTech filter so as to avoid exposing others to foreseeable and unreasonable risks of harm.
- 53. Defendants knew or reasonably should have known that the VenaTech filter was dangerous or was likely to be dangerous when used in its intended or reasonably foreseeable manner.
- 54. At the time of manufacture and sale of the VenaTech filter (May 2001 until Present), Defendants knew or should have known that the VenaTech filter:

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- a. Was designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device;
- b. Was designed and manufactured so as to present an unreasonable risk of migration of the device and/or portions of the device;
- c. Was designed and manufactured so as to present an unreasonable risk of the device tilting and/or perforating the vena cava wall;

- d. Was designed and manufactured so as to present an unreasonable risk of causing thrombosis; and/or,
- e. Was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body.
- 55. At the time of manufacture and sale of the VenaTech filter (May 2001 until Present), Defendants knew or should have known that using the VenaTech filter in its intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe health side effects, including, but not limited to: thrombosis; occlusion of the vena cava hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissues, vessels and organs; and other severe personal injuries and diseases which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the device; and, the continued risk of requiring additional medical and surgical procedures, including general anesthesia, with attendant risk of life threatening complications.
- 56. Defendants knew or reasonably should have known that consumers of the VenaTech filter would not realize the danger associated with using the device in its intended use and/or in a reasonably foreseeable manner.
- 57. Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the VenaTech filter in, among others, the following ways:

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a. Designing and distributing a product which the Defendants knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

- b. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other devices available for the same purpose;
- c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;
- d. Failing to use reasonable care to warn or instruct, including pre- and postsale, Plaintiff, Plaintiff's physicians, Plaintiff's agents or the general healthcare community about the VenaTech filter's substantially dangerous condition or about facts making the product likely to be dangerous;
- e. Failing to perform reasonable pre- and post-market testing of the VenaTech filter to determine whether or not the product was safe for its intended use;
- f. Failing to provide adequate instructions, guidelines, and safety precautions, including pre- and post-sale, to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the VenaTech filter;
- g. Advertising, marketing and recommending the use of the VenaTech filter, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with and inherent in the use of the VenaTech filter;
- h. Representing that the VenaTech filter was safe for its intended use when in fact, Defendants knew and should have known the product was not safe for its intended purpose;
- i. Continuing to manufacture and sell the VenaTech filter with the knowledge that the product was dangerous and not reasonably safe;
- j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the VenaTech filter so as to avoid the risk of serious harm associated with the use of the VenaTech filter;
- k. Advertising, marketing, promoting and selling the VenaTech filter for uses other than as approved and indicated in the product's label;
- 1. Failing to establish an adequate quality assurance program used in the manufacturing of the VenaTech filter; and
- m. Failing to establish and maintain an adequate post-market surveillance program.

- 58. A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.
- 59. As a direct and proximate result of the foregoing negligent acts and omissions by the Braun Defendants, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

COUNT II STRICT PRODUCTS LIABILITY - FAILURE TO WARN

- 60. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.
- 61. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the VenaTech filter, including the one implanted in Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers.
- 62. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, Defendants knew or should have known the device presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use. Specifically, Defendants knew or should have known at the time they manufactured, labeled, distributed and sold the VenaTech filter, which was implanted into Plaintiff, that the VenaTech filter, *inter alia*, posed a significant and higher risk than other similar devices of device failure (fracture, migration, tilting, causing thrombosis, and/or perforation of the vena cava wall) and resulting serious injuries.
- 63. Consequently, Defendants had a duty to warn of the risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device.

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- 64. Defendants further had a duty to warn of dangers and proper safety instructions that they became aware of even after the device was distributed and implanted into Plaintiff.
- 65. Despite their duties, Defendants failed to adequately warn of material facts regarding the safety and efficacy of the VenaTech filter, and further failed to adequately provide instructions on the safe and proper use of the device.
- 66. No healthcare provider, including Plaintiff's, patient or patient's agent would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers and/or ultimate users of the device.
- 67. The health risks associated with the device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.
- 68. Plaintiff and Plaintiff's healthcare providers used the device in a normal, customary, intended, and foreseeable manner, namely as a surgically implanted device used to prevent pulmonary emboli.
- 69. Therefore, the VenaTech filter implanted in Plaintiff was defective and unreasonably dangerous at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.
- 70. The VenaTech filter implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.
- 71. As a direct and proximate result of Defendants' lack of sufficient warning and/or instructions, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

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COUNT III STRICT PRODUCTS LIABILITY – DESIGN DEFECT

- 72. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.
- 73. At all times relevant to this action, Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, sold, and distributed into the stream of commerce the VenaTech filter, including the one implanted in Plaintiff.
- 74. The VenaTech filter was expected to, and did, reach its intended consumers without substantial change in the condition it was in when it left Defendants' possession. In the alternative, any changes that were made to VenaTech filter implanted in Plaintiff were reasonably foreseeable to Defendants.
- 75. The VenaTech filter implanted in Plaintiff was defective in design because it failed to perform as safely as persons who ordinarily use the product would have expected at the time of use.
- 76. The VenaTech filter implanted in Plaintiff was defective in design, in that its risks of harm exceeded its claimed benefits.
- 77. Plaintiff and Plaintiff's healthcare providers used the VenaTech filter in a manner that was reasonably foreseeable to Defendants.
- 78. Neither Plaintiff nor Plaintiff's healthcare providers could have, by the exercise of reasonable care, discovered the device's defective condition or perceived its unreasonable dangers prior to Plaintiff's implantation with the device.
- 79. As a direct and proximate result of the VenaTech filter's defective design, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

COUNT IV <u>STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT</u>

- 80. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.
- 81. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the VenaTech filter that was implanted into Plaintiff.
- 82. The VenaTech filter implanted in Plaintiff contained a condition or conditions, which Defendants did not intend, at the time it left Defendants' control and possession.
- 83. Plaintiff and Plaintiff's healthcare providers used the device in a manner that was reasonably foreseeable to Defendants.
- 84. As a result of the condition or these conditions, the product injured Plaintiff and failed to perform as safely as the ordinary consumer would expect when used in a reasonably foreseeable manner.
- 85. As a direct and proximate result of the VenaTech filter's manufacturing defects, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

COUNT V BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

- 86. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.
- 87. At all times relevant to this action, Defendants designed, researched, developed, manufactured, tested, labeled, inspected, advertised, promoted, marketed, sold, and distributed into the stream of commerce the VenaTech filter for use as a surgically implanted device used to

prevent pulmonary embolisms and for uses other than as approved and indicated in the product's instructions, warnings, and labels.

- 88. At the time and place of the sale, distribution, and supply of the Defendants' VenaTech filter to Plaintiff by way of Plaintiff's healthcare providers and medical facilities, Defendants expressly represented and warranted, by labeling materials submitted with the product, that the VenaTech filter was safe and effective for its intended and reasonably foreseeable use.
- 89. Defendants knew of the intended and reasonably foreseeable use of the VenaTech filter at the time they marketed, sold, and distributed the product for use by Plaintiff, and impliedly warranted the product to be of merchantable quality and safe and fit for its intended use.
- 90. Defendants impliedly represented and warranted to the healthcare community, Plaintiff and Plaintiff's healthcare providers, that the VenaTech filter was safe, of merchantable quality and fit for the ordinary purpose for which the product was intended and marketed to be used.
- 91. The representations and implied warranties made by Defendants were false, misleading, and inaccurate because the VenaTech filter was defective, unsafe, unreasonably dangerous, and not of merchantable quality, when used in its intended and/or reasonably foreseeable manner. Specifically, at the time of Plaintiff's purchase of the VenaTech filter from the Defendants, through Plaintiff's physicians and medical facilities, it was not in a merchantable condition in that:
 - a. It was designed in such a manner so as to be prone to an unreasonably high rate of failure, including fracture, migration, excessive tilting, causing thrombosis and/or perforation of bodily organs;
 - b. It was designed in such a manner so as to result in an unreasonably high rate of injury to the organs and anatomy; and,
 - c. It was manufactured in such a manner so that the VenaTech Filter System was inadequately, improperly and inappropriately prepared and/or finished, so as

to be prone to an unreasonably high rate of failure and/or causing the device to fail.

- 92. Plaintiff and Plaintiff's healthcare providers reasonably relied on the superior skill and judgment of Defendants as the designers, researchers and manufacturers of the product, as to whether the VenaTech filter was of merchantable quality, safe and fit for its intended use and also relied on the implied warranty of merchantability and fitness for the particular use and purpose for which the VenaTech filter was manufactured and sold.
- 93. Defendants placed the VenaTech filter into the stream of commerce in a defective, unsafe, and unreasonably dangerous condition, and the product was expected to and did reach Plaintiff without substantial change in the condition in which the VenaTech filter was manufactured and sold.
- 94. Defendants breached their implied warranty because their VenaTech filter was not fit for its intended use and purpose.
- 95. As a proximate result of Defendants breaching their implied warranties, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

COUNT VI NEGLIGENT MISREPRESENTATION

- 96. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.
- 97. At all times relevant to this cause, and as detailed herein, Defendants negligently provided Plaintiff's healthcare providers, and the general medical community with false or incorrect information, or omitted or failed to disclose material information concerning the VenaTech filter; including, but not limited to, misrepresentations relating to the safety, efficacy, failure rate and approved uses of the VenaTech filter.

- 98. The information distributed by Defendants to the public, the medical community and Plaintiff's healthcare providers, including reports, press releases, advertising campaigns, labeling materials, print advertisements, and commercial media containing material representations was false and misleading, and contained omissions and concealment of truth about the dangers of the use of the VenaTech filter. Defendants made the foregoing misrepresentations knowing that they were false and/or without reasonable basis in fact. These materials included instructions for use and warning document that was included in the package of the VenaTech filter that was implanted in Plaintiff.
- 99. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff's healthcare providers; to gain the confidence of the public and the medical community, including Plaintiff's healthcare providers; to falsely assure them of the quality of the VenaTech filter and its fitness for use; and to induce the public and the medical community, including Plaintiff's healthcare providers, to request, recommend, prescribe, implant, purchase, and continue to use the VenaTech filter.
- 100. The foregoing representations and omissions by Defendants were in fact false. The VenaTech filter is not safe, fit, or effective for human use in its intended and reasonably foreseeable manner. The use of the VenaTech filter is hazardous to the user's health, and said device has a serious propensity to cause users to suffer serious injuries, including, without limitation, the injuries Plaintiff suffered. Further, the device has a significantly higher rate of failure and injury than do other comparable devices.
- 101. In reliance upon the false and negligent misrepresentations and omissions made by Defendants, Plaintiff's healthcare providers, and the Plaintiff's agents were induced to,

and did use the VenaTech filter, thereby causing Plaintiff to sustain severe and permanent personal injuries.

- 102. Defendants knew and had reason to know that Plaintiff's healthcare providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by Defendants, and would not have prescribed and implanted same, if the true facts regarding the device had not been concealed and misrepresented by Defendants.
- 103. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who are implanted with the VenaTech filter.
- 104. At the time Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff used the VenaTech filter, Plaintiff, Plaintiff's healthcare providers and the Plaintiff's agents were unaware of Defendants' negligent misrepresentations and omissions.
- 105. Plaintiff's healthcare providers, Plaintiff's agents, and the general medical community reasonably relied upon misrepresentations and omissions made by Defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the VenaTech filter.
- 106. Plaintiff's healthcare provider's, and Plaintiff's agents' reliance on the foregoing misrepresentations and omissions by Defendants' were the direct and proximate cause of Plaintiff's injuries as described herein.

COUNT VII PUNITIVE DAMAGES ALLEGATIONS

107. Plaintiff re-alleges each and every allegation in their Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

108. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total reckless disregard for the public safety and welfare.

109. Defendants had knowledge of, and were in possession of, evidence demonstrating that the VenaTech filter was defective, unreasonably dangerous, and had a substantially higher failure rate than did other similar devices on the market. Despite their knowledge, Defendants failed to, among other purposeful acts, inform or warn Plaintiff or his healthcare providers of the dangers, establish and maintain an adequate quality and post-market surveillance system, and recall the VenaTech filter from the market.

110. As a direct, proximate, and legal result of Defendants' acts and omissions as described herein, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

PRAYER FOR DAMAGES

WHEREFORE, Plaintiff Kevin Hamblin prays for relief on the entire complaint, as follows:

- a. Judgment to be entered against all Defendants on all causes of action of his Complaint, including, but not limited to:
 - 1. Physical pain and suffering in the past and which, in reasonable probability, he will continue to suffer in the future;
 - 2. Physical impairment and incapacity in the past and which, in reasonable probability, he will continue to suffer in the future;
 - 3. Mental anguish in the past and which, in reasonable probability, he will sustain in the future;
 - 4. Reasonable and necessary medical expenses for treatment received in the past and, based upon reasonable medical probability, the reasonable medical expenses he will need in the future;

- 5. Disfigurement in the past and which, in reasonable probability, he will continue to suffer in the future;
- 6. Loss of earning capacity and wages in the past and future; and,
- 7. Punitive damages (as to the Braun Defendants only).
- b. Plaintiff be awarded full, fair, and complete recovery for all claims and causes of action relevant to his action;
- c. Plaintiff be awarded all appropriate costs, fees, expenses, and pre-judgment and post-judgment interest pursuant to the laws of the State of Pennsylvania as authorized by law on the judgments entered in Plaintiff's behalf; and,
- d. Such other relief the court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

Dated: July 15, 2021. Respectfully Submitted,

LAW OFFICES OF BEN C. MARTIN

/s/ Ben C. Martin

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ATTORNEYS FOR PLAINTIFF

CERTIFICATE OF SERVICE

I, Ben C. Martin, hereby certify that on the 15th day of July 2021, I served a true and correct copy of Plaintiff's Complaint on all counsel of record via the Court's electronic filing system.

/s/ Ben C. Martin
Ben C. Martin, Esq.

VERIFICATION

I, Ben C. Martin, attorney for Plaintiff, verify that verification of the Plaintiff cannot be

obtained with the time allowed for filing the pleading. I further verify that the statements made in

the foregoing Complaint are true and correct to the best of my knowledge, information and belief.

I understand that false statements herein are made subject to the penalties of 18 Pa.C.S. § 4904

relating to unsworn falsification to authorities.

Dated: July 15, 2021 /s/ Ben C. Martin

Ben C. Martin (PA No. 320123)

Attorney for Plaintiff